

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s):	Michael Wandell et al.	Examiner:	Lore Ramillano
Application No.:	10/706,321	Art Unit:	1797
Filing Date:	November 12, 2003	Docket No.:	36664.00.0013
Confirmation No.:	6492		

Title: **QUANTITATIVE ANALYSIS OF A BIOLOGICAL SAMPLE OF
UNKNOWN QUANTITY**

Mail Stop AF
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF

Dear Sir:

Pre-Appeal is respectfully requested. Applicant files this Pre-Appeal Brief along with a Notice of Appeal. Pre-appeal review is the proper recourse when a rejection is based either on a clear error in law or when the Examiner fails to set forth a *prima facie* case against patentability, omitting one or more elements or limitations required in a claim. See *OG Notice*, July 12, 2005, New Pre-Appeal Brief Conference Pilot Program. In this case, the Examiner argues as part of the *prima facie* case that by drawing a small circle using a pen on a flat, continuous sheet of paper, an "aperture" having a "blood receiving opening" is created in the paper.

As a reminder, all remaining claims (claims 4–15, 20–21, and 42) stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Quattrocchi (U.S. Patent No. 6,014,438) in view of Fitzgerald et al. (U.S. Patent No. 6,528,321). Claims 4, 6, and 42 are independent and include the aperture and opening discussed hereafter as part of claim 4. Applicant has made several arguments during prosecution, and these substantive arguments are reserved for the appeal process. The Examiner's confusion as to how drawn marks can be apertures is particularly adapted to the pre-appeal process as being an abuse of discretion. Claim 4 provides the following:

4. A fluid collection device comprising a fluid collector with an absorbent substrate coated with a saccharide, said substrate comprising a mat of glass fibers at least substantially coated with polyvinyl alcohol, said fibers defining a plurality of pores, the pores in said mat having a pore size effective to at least substantially prevent lysing of red blood cells while permitting at least substantial separation of serum from red blood cells via differential wicking and a superstrate, said fluid collector being generally fixed with respect to said superstrate, said superstrate having an aperture defining a blood receiving opening and permitting access to said fluid collector.

Applicant's Fig. 9 reproduced below illustrates the fluid collection device 900 where two fluid collectors 903 and 904 are disposed over a fixed superstrate 905. Two apertures 909 and 910 allow users to prick their fingers and place the bleeding finger on the fluid collector directly through what is called blood-receiving openings. The shaded portion between the large arrows is tainted with blood from the finger, and as the blood migrates up the fluid collectors, a user will see a portion of the fluid collector through the secondary apertures turn red 911, 912 with blood. On this device, small strips are used and stabilized using the superstrate.

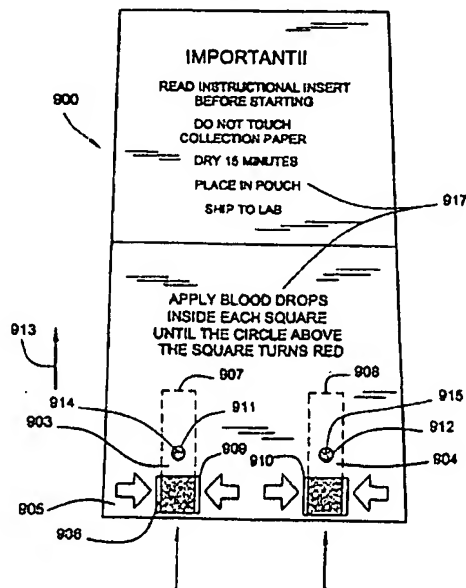
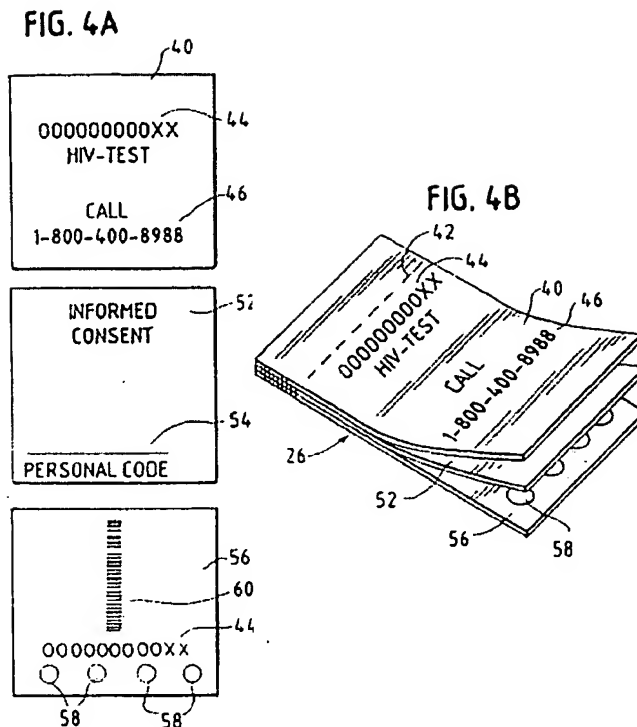


Fig. 9 of Application No. 10/706,321

In the *prima facie* case, the Examiner cites U.S. Patent No. 6,014,438 (Quattrocchi). Quattrocchi is a decade-old technology owned by Applicant. Figures 4A and 4B of the fluid collection device of that reference are shown below.



This older technology is simpler and has obvious disadvantages. Subsequent to a request for reconsideration, Applicant brought the following portion of the Quattrocchi specification to the attention of the Examiner in a phone conversation:

FIGS. 4A and 4B schematically illustrate one form of blood specimen collection card 26 which is preferably configured in a diagnostic form having three (3) parts. The first part is a removable top sheet 40. Perforations 42 are preferably provided to enable the person being tested to remove the top sheet 40 from the remainder of the collection card 26. Printed on the top sheet 40 is information that the person being tested needs to retrain after the remainder of the collection card 26 is sent for analysis. Col. 6, ll. 54-63.

The second part of collection card 26 is an informed consent form 52. The informed consent form 52 contains a series of statements that the person being tested must read, understand, and acknowledge before a laboratory can perform any test on the specimen. Col. 7, ll. 23-26.

In its illustrated form, the third part of collection card 26 is a blood specimen sample sheet 56. Sample sheet 56 is at least in part a cotton fiber filter paper preferably like that manufactured by Schleicher and Schuell. Sample sheet 56 has a blood collection area specifically designated thereon. In the illustrated embodiment, four similarly shaped sections 58 are outlined thereon for deposit of a specimen in each section. The sections 58 are outlined using black biological ink so that the ink will not interfere with the specimen and an accurate test result can be obtained. Col. 7, ll. 32-42 (emphasis added).

The old technology requires the entire sheet to be made of expensive blood-retaining media. Ink circles are drawn on a flat piece of paper, and users were required to place the finger in the circle and try to get the blood to diffuse over the entire area of the circle. There is no built-in protection for the blood sample, and it would then be mailed and rub directly against other bodies during transportation. Once at the laboratory, a circular punch system was used to remove the surface area inside the ink circles to collect the part of the substrate to dilute for measurement. If part of the circle was still white, the measure would be skewed.

The Examiner's position is best summarized by the continuation comment to the Advisory Action of September 11, 2008: "the Office takes the position that specimen sections (58) may be broadly interpreted to be openings. Furthermore, it appears that Quattrocchi's apertures read on applicant's apertures since applicant's apertures, like Quattrocchi, are filled with the fluid collector material, which includes an absorbent substrate."

During patent examination, pending claims must be given their broadest reasonable interpretation consistent with the specification. *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005). Words of a claim must be given their plain meaning unless this meaning is inconsistent with the specification. *In re Zletz*, 893 F.2d 319 (Fed. Cir. 1989). The *Merriam-Webster's Collegiate Dictionary*, 10th ed. defines "aperture" as an opening or open space: hole. In turn, "opening" is defined as something that is open. (See Exhibit A attached hereto).

In *Mechanics of Patent Claim Drafting*, 2nd. ed., Landis explains, "Do not claim holes positively or make them claim elements. Holes are nothing; you cannot claim nothing. Claim "[member] having a hole, groove, slot, aperture, etc." Section 23. A copy of the relevant pages from this reference is attached as Exhibit B. Applicant respected this suggested format to claim the hole as an aperture of the superstrate and wrote, "... said superstrate having an aperture defining a blood receiving opening and permitting access to said fluid collector." The claim language is perfectly clear.

The Examiner confuses a structure having a fluid collector, a substrate, and a superstrate, with the aperture on the superstrate. Quattrocchi is a structure with a fluid collector and a superstrate and no apertures on either the fluid collector or the substrate.

Rules are given to the Examiner if she wants to constitute a valid *prima facie* case where ink circles constitute apertures. She must either prove that Applicant's specification supports this particular meaning—that the plain meaning of these words support this interpretation—or that one of ordinary skill in the art agrees with the Examiner. MPEP § 2111. The position taken by the Examiner is contrary to almost every patent claim recorded with this Office. Apertures and openings in a media are precisely that: an aperture or an opening. Applicant asks this Board under what possible circumstance can writing or printing the number 8 on a piece of paper result in an apparatus with two apertures or two openings?

The use of the term "aperture" and "opening" is well established under modern patent practice. Apertures and openings are normal terminology used to claim holes. The plain meaning of these words is well known and unambiguous. Quattrocchi is a device with a fluid collector without neither an aperture nor an opening. The Examiner's position is contrary to common sense and patent law. The Examiner cannot argue that Applicant's apertures should be broadly construed to include surface areas within ink circles. Accordingly, Applicant requests reconsideration and withdrawal of the rejection and issuance of a Notice of Allowance for all claims.

Respectfully submitted,

By:

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Date: September 23, 2008

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Merriam- Webster's Collegiate[®] Dictionary

TENTH EDITION

Merriam-Webster, Incorporated
Springfield, Massachusetts, U.S.A.

ap-a-ra-jo *wa-pa-'rá-(i)(h)õ* *n. pl* -jos [AmerSp] (1844): a packsaddle of stuffed leather or canvas

ly|sing|lō|go|lō|law|lō|l|boy|th|thin|th|the|ū|loot|ù|foot
ly|yct|zh|vision|lá, k, °, æ, œ, w, ū, ʔ see Guide to Pronunciation

a : enterable by both amateur and professional contestants (an ~ tournament) b : enterable by a registered voter regardless of political affiliation (an ~ primary) 6 : fit to be traveled over : presenting no obstacle to passage or view (the ~ road) 7 : a country ~ having the parts or surfaces laid out in an extended position : spread out : UNFOLDED (an ~ book) 8 (1) LOW 13 (2) : formed with the tongue in a lower position (climpaired by undue tension or constriction of the throat (an ~ laryngeal tone)) (2) of a tone : produced by an open string or on a wind instrument by the lip without the use of slides, valves, or keys 9 a : available to follow or make use of (the only course ~ to us) b : not taken up with duties or engagements (keep an hour ~ on Friday) c : not finally decided : subject to further consideration (the salary is ~) (an ~ question) d : available for a qualified applicant : VACANT (the job is still ~) e : remaining available for use or filling until canceled (an ~ order for more items) f : available for future purchase (these items are in ~ stock) 10 a : characterized by ready accessibility and usu. generous attitude as : (1) : generous in giving (a ~ heart) (2) : willing to hear and consider or to accept and deal with : RESPONSIVE (3) : free from reserve or pretense : FRANK b : accessible to the influx of new factors (as foreign goods) (an ~ market) 11 a : having openings, interruptions, or spaces (a ~ mesh) as : (1) : being porous and friable (~ soil) (2) : sparsely distributed : SCATTERED (~ population) (3) of a sound : having components separated by a space in writing or printing (as *opaque projector*) b : not made up of a continuous closed circuit of channels (the insect circulatory system is ~) 12 a of an organ pipe : not stopped at the top b of a string on a musical instrument : not stopped by the finger 13 : being in operation (an ~ microphone) : esp : ready for business, patronage, or use (the store is ~ from 9 to 5) (the new highway will be ~ next week) 14 a (1) : characterized by lack of effective regulation of various commercial enterprises (an ~ town) (2) : not repressed by legal controls (~ gambling) b : free from checking or hampering restraints (an ~ economy) c : relatively ungaurded by opponents (passed the ~ by the teammate) 15 : having been opened by a first ante, bet, or bid (the bidding is ~) 16 of punctuation : characterized by sparing use esp. of the comma 17 a : containing none of its points (an ~ interval) b : being a set or composed of sets none of which has a neighborhood all of whose points are contained in the set (the interior of a sphere is an ~ set) c : being an incomplete electrical circuit b : not allowing the flow of electricity (an ~ switch) *syn* *see* FRANK, Liable — *open* *adv* — *openly* \ˈō-pən-lē *adv* — *openness* -nəs

open *vb* opened \ˈō-pənd, -ˈō-pˈmnd/; *opening* \ˈōp-nŋ, -ˈō-pə- *v* (bef. 12c) 1 a : to move (as a door) from a closed position b : to make available for entry or passage by turning back (as a barrier) or removing (as a cover or an obstruction) 2 a : to make available for or active in a regular function (~ a new store) b : to make accessible for a particular purpose (~ed new land for settlement) (~ the way for changes) c : to initiate access to (a computer file prior to use) 3 a : to disclose or expose to view : REVEAL b : to make more discerning or responsive : ENLIGHTEN (must ~ our minds to the problems) c : to bring into view or come into sight of by changing position 4 a : to make an opening in (~ed the boiler) b : to loosen and make less compact (~ the soil) 5 : to spread out : UNFOLD (~ed the book) 6 a : to enter upon : BEGIN (~ed the meeting) b : to commence action in a card game by making (a first bid), putting a first bet in (the pot), or playing (a card or suit) as first lead 7 : to restore or recall (as an order) from a finally determined state to a state in which the parties are free to prosecute or oppose ~ *vi* 1 : to become open (the office ~ed early) 2 a : to spread out : EXPAND (the wound ~ed under the strain) b : to become disclosed (a beautiful vista ~ed before us) 3 : to become enlightened or responsive 4 : to give access (the rooms ~ onto a hall) 5 : SPEAK OUT 2 (finally he ~ed freely on the subject) 6 : to begin a course or activity (the play ~ed on Tuesday) 7 : to make a bet, bid, or lead in becoming a round or hand of a card game — *open-abled* -tī \ˈōp-ə-ˈbi-l-ē, -ˈō-pə- *n* — *open-able* \ˈōp-nə-bəl, -ˈō-pə- *adj*

open *n* (13c) 1 : OPENING 2 : open and unobstructed space : as a : OPEN AIR b : open water 3 : an open contest, competition, or tournament 4 : a public or unconcealed state or position — *open admission* *n* (1969) : OPEN ENROLLMENT 2 — *open-air* *adj* (1830) : OUTDOOR — *open air* *n* (15c) : the space where air is unconfined; *esp* : OUTDOORS — *open-and-shut* *adj* (1841) 1 : perfectly simple : OBVIOUS 2 : easily settled (~ an case) — *open bar* *n* (1973) : a bar (as at a wedding reception) at which drinks are served free — compare CASH BAR — *open-fast* \ˈōp-ən-ˈkɑst/ *adj* (ca. 1890) chiefly Brit : worked from a surface open to the air (as in ~ mine) (~ mining) — *open chain* *n* (1884) : an arrangement of atoms represented in a structural formula by a chain whose ends are not joined so as to form a ring open city *n* (1914) : a city that is not occupied or defended by military forces and that is ~ not allowed to be bombed under international law — *open ending* *n* (1971) : the marking of perishable food products with a clearly readable date indicating when the food was packaged or the last date on which it should be sold or used — *open door* *n* (1526) 1 : a recognized right of admittance : freedom of access 2 : a policy giving opportunity for commercial relations with a country to all nations on equal terms — *open-door* *adj* — *open-end* *adj* (1917) : organized to allow for contingencies : as a : permitting additional debt to be incurred under the original indenture subject to specified conditions (an ~ mortgage) b : having a fluctuating capitalization of shares that are issued or redeemed at the current net asset value or at a figure in fixed ratio to this (an ~ investment company) — compare CLOSED-END — *open-ended* \ˈōp-ən-ˈen-dəd/ *adj* (1825) 1 : not rigorously fixed : as a : adaptable to the developing needs of a situation b : permitting or designed to permit spontaneous and unguided responses — *open-endedness* -nəs

open *enrollment* *n* (1964) 1 : the voluntary enrollment of a student in a public school other than the one assigned on the basis of residence 2 : enrollment on demand as a student in an institution of higher learning irrespective of formal qualifications

open-er *ˈɒp-nər, ˈɒ-pə-n* *n* (15c): one that opens (a bottle ~): as *a pl*; cards of sufficient value for a player to open the betting in a poker game ~ the first item, contest, or event of a series — *for* **open-ers**: to begin with
open-eyed *ˈɒp-n̩-tɪd* *adj* (1601) 1: having the eyes open 2: carefully observant: DISCERNING
open-handed *ˈɒp-n̩-dəd* *adj* (1593): GENEROUS, MUNIFICENT — **open-handed-ly** *adv* — **open-handed-ness** *n*
open-heart *adj* (1960): of, relating to, or performed on a heart temporarily relieved of circulatory function and surgically opened for inspection and treatment (~ surgery)
open-heart-ed *ˈɒp-n̩-ˈhɑː-təd* *adj* (1611) 1: candidly straightforward: FRANK 2: responsive to emotional appeal — **open-heart-ed-ly** *adv* — **open-heart-ed-ness** *n*
open-hearth *adj* (1885): of, relating to, involving, or produced in the open-hearth process (~ steel)
open-hearth process *n* (1882): a process of making steel from pig iron in a furnace of the regenerative reverberatory type
open house *n* (17c): ready and usu. informal hospitality or entertainment for all comers 2: a house or apartment open for inspection esp. by prospective buyers or tenants
open-ing *ˈɒp-nɪŋ, ˈɒ-pə-n* (13c) 1a: an act or instance of making or becoming open *b*: an act or instance of beginning: COMMENCEMENT; esp.: a formal and usu. public event by which something new is put officially into operation 2: something that is open: as (1) BREACH, APERTURE (2): an open width: SPAN *b*: an area without trees or with scattered usu. mature trees that occurs as a break in a forest *c*: two pages that face one another in a book 3: something that constitutes a beginning: as *a*: a planned series of moves made at the beginning of a game of chess or checkers — compare **ENDGAME**, **MIDDLE GAME** *b*: a first performance 4a: OCCASION, CHANCE *b*: an opportunity for employment
open letter *n* (1878): a published letter of protest or appeal usu. addressed to an individual but intended for the general public
open loop *n* (1947): a control system for an operation or process in which there is no self-correcting action as there is in a closed loop
open marriage *n* (1971): a marriage in which the partners agree to let each other have sexual partners outside the marriage
open-minded *ˈɒp-n̩-mɪndəd* *adj* (1828): receptive to arguments or ideas — **open-minded-ly** *adv* — **open-minded-ness** *n*
open-mouthed *ˈɒp-n̩-maʊtɪd, ˈmaʊtɪd* *adj* (15c) 1: CLAMOROUS, VOCIFEROUS 2: having the mouth wide open 3: struck with amazement or wonder — **open-mouth-ed-ly** *adv* *ˈmaʊ-tʃəd-li, -tʃəd-ɪ* — **open-mouth-ed-ness** *ˈmaʊ-tʃəd-nəs, -tʃəd-ɪ* *n*
open-poll-i-nat-ed *ˈɒp-n̩-pɒ-lɪ-n̩-təd* *adj* (1925): pollinated by sexual agencies without human intervention
open season *n* (ca. 1890) 1: a period when it is legal to kill or catch game or fish protected at other times by law 2: a time during which someone or something is the object of sustained attack or criticism
open secret *n* (1828): a supposedly secret but generally known matter
open sentence *n* (1837): a statement (as in mathematics) that contains at least one blank or unknown and that becomes true or false when the blank is filled or a quantity is substituted for the unknown
open ses-a-me *ˈɒp-sə-sə-mē* *n* [*fr.* *open sesame*, the magical command used by Ali Baba to open the door of the robbers' den in *Ali Baba and the Forty Thieves*] (ca. 1837): something that unfailingly brings about a desired end
open shop *n* (1903): an establishment in which eligibility for employment and retention on the payroll are not determined by membership or nonmembership in a labor union though there may be an agreement by which a union is recognized as sole bargaining agent
open sight *n* (1591): a firearm rear sight having an open notch
open stance *n* (1948): a stance (as in golf) in which the forward foot is farther from the line of play than the back foot — compare **CLOSED STANCE**
open syllable *n* (1891): a syllable ended by a vowel or diphthong
open up *vi* (1582) 1: to make available 2: to make plain or visible: DISCLOSE 3: to open by cutting into ~ *vt* 1: to spread out or open into (the road *opens up* ahead) 2: to commence firing 3: to become communicative (tried to get the patient to *open up*)
open-work *ˈɒp-n̩-ˈwɜːk* *n*, *often attrib* (1598): work constructed so as to show openings through its substance: work that is perforated or pierced (wrought-iron ~) — **open-worked** *v*, *workt* *adj*
opera *pl* of **opus**
ˈɒp-ə *ˈvā-pə-rə, Southern also ˈvā-prē* *n* [*It.* *work, opera*, *fr. L.* *work, plays*; akin to *L. oper, opus* — more at **OPERATE**] (1644) 1: a dramatic poem set to music and made up of vocal pieces with orchestral accompaniment and orchestral overtures and interludes; *specif.* GRAND OPERA 2: the score of a musical drama 3: the performance of an opera *adj*: a house where operas are performed
op-er-a-ble *ˈvā-pə-rə-bəl* *adj* (1646) 1: fit, possible, or desirable to use: PRACTICABLE 2: likely to result in a favorable outcome: operable surgical treatment (an ~ cancer) — **op-er-a-bil-i-ty** *ˈvā-pə-rə-bil-i-ti* *n*
ˈɒp-ə *ˈbʊf-ə* *ˈvā-pə-rə-bʊf, fr. ˈvā-pə-rə* *n* [*Fr.* *It. opera buffa*] (1778): satirical comic opera
opera bu-fa *ˈvā-bʊ-fə* *n* [*It.* *lit., comic opera*] (1802): an 18th-century farical comic opera with dialogue in recitative
op-er-a *ˈvā-pə-rə* *n* [*It.* *lit., comic opera*] (1744): an 18th-century opera characterized by spoken dialogue interspersed between the acts and ensemble numbers — compare **GRAND OPERA**
opera glass *n* (1738): a small low-power binocular without prism lens use at the opera or theater — often used in *pl.*
op-er-a-go-er *ˈvā-pə-rə-gō-ŋər* *n* (1850): a person who frequently goes to operas — **op-er-a-go-ŋ *v* *ˈvā-pə-rə-gō-ŋ* *n*
opera hat *n* (1810): a man's collapsible top hat
opera house *n* (1720): a theater devoted principally to the performance of operas; *broadly*: THEATRE
op-er-a-tion *ˈvā-pə-rən* *n* [*L. operandum*, *neut.* of gerundive of *operari* (1886): something (as a quantity or data) that is operated on (as in a mathematical operation); also: the address in a computer instruction of data to be operated on
ˈɒp-er-ant *ˈvā-pə-rən-t* *adj* (15c) 1: functioning or tending to produce effects: EFFECTIVE (an ~ conscience) 2: of or relating to the act of**

[illegible]

MECHANICS OF PATENT CLAIM DRAFTING

Second Edition

Eighth Printing

John L. Landis

With the Collaboration of
John D. Kaufmann, Bryan W. Sheffield
and Myron Cohen

G7-1009
Practising Law Institute
New York City

popper and is to be so claimed, and that the holes in the container (Fig. 1) are important and must be defined.

Clause (a) of Claim 1 might read:

A container for receiving kernels of corn to be popped, the container having a perforated bottom with apertures smaller in size than the kernels;

Other examples of expressions defining features of elements:

a disc of resilient material having a peripheral groove...

a relay having two windings...

a lever having a forked end and a rounded end... [If only the forked end is important to the combination being claimed, do not mention the rounded end.]

a gear of electrically insulating material...

If an element by definition inherently includes a certain feature, such feature need not be recited and it is proper to refer, without previous mention, to such features as:

the end of the lever...

the periphery of the disc...

the tines of the fork...

In case of doubt, positively describe the feature or part.

SUMMARY—Select those parts or features of each element that are essential to the combination being claimed. Then, describe them in a logical order, preferably following the main description of the element in the same clause of the claim. How many features need to be described and how broadly each should be recited is a matter of claim scope (based largely on the prior art), but the principles are the same as used in selecting the elements and naming them.

Section 23—Claiming Holes

In the situation where a hole is to be described it must not be recited positively. That is, instead of stating "a hole, groove, aper-

ture, recess, slot, etc., in the lever," one must state "... the lever having a hole, groove, etc." Thereafter, one can refer to "the hole" or "said hole." This "rule" may seem to make little sense, but it is another founded in antiquity like the single-sentence rule. Maybe someone thought that a hole is nothing—and people shouldn't claim nothing?

Another approach to describing holes is an expression such as "... the level having portions defining a hole, groove, etc." The hole is thus defined in terms of the structure which forms it.

One case *In re Newton*, 163 USPQ 34 (CCPA 1969), held that it was proper to claim a hole and its function as a means for performing a function, specifically "means for providing fluid communication between . . . [two members]."

SUMMARY—Do not claim holes positively or make them claim elements. Holes are nothing; you cannot claim nothing. Claim "a [member] having a hole," groove, slot, aperture, etc.

Section 24—Order of Elements

The elements of the claim should be presented in some logical order. Often, there are several orders that make sense, and any one may be selected. The order used in Claim 1 is a "functional" order, starting with the element which first contacts the work-piece (the container) and proceeding along functional lines to describe the remaining elements.

Another order which is often used is a "structural" order, starting first with the base, or the source of power, and proceeding along structural lines to describe the remaining elements. In structural order, Claim 1 would read:

1B. Apparatus for shaking articles, which comprises:

- (a) a base;
- (b) a plurality of parallel legs, each of which is connected pivotally at one end of the base;
- (c) a container for the articles connected pivotally to the other ends of the legs, so that the legs support the container for oscillating movement with respect to the base; and

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